

### **REMARKS**

Claims 1-8, 21, 22, 24-29, 34-36, 49, 56, 58, 62, 64, and 69-82 are pending and stand variously rejected under 35 U.S.C. §§ 112 and 103. Claim 1 has been amended herein to make explicit that the *lux* polynucleotides are derived from an organism in which the naturally occurring arrangement of the *lux* operon is *luxCDABE*, as described throughout the specification as filed, for example on page 1, lines 10-13 and lines 18-21. Claims 6-8 and 25-27 have been amended to reference specific sequence identifiers. Claims 74-76 have been amended to correct a typographical error. The amendments are made in a sincere effort to advance prosecution. Thus, claims 1-8, 21, 22, 24-29, 34-36, 49, 56, 58, 64, and 69-82 are pending.

The foregoing amendments are not intended to be an acquiescence in the Office's assessment of those claims in the Final Office action, and Applicants expressly reserve the right to bring the subject matter of the original claims again in a subsequent, related application. Entry of the foregoing amendments is respectfully requested.

### **Claim Objections**

The Examiner has objected to claims 74-76 for referring to a bacteria instead of a bacterium. By amendment herein, this typographical error has been corrected and the objections obviated.

### **35 U.S.C. § 112, First Paragraph, Written Description**

Claims 1-3, 5-8, 21, 22, 24-28, 34-36, 49, 56, 58, 64 and 69-82 stand rejected as allegedly not described in sufficient structural or functional detail. (Final Office Action, pages 2-3).

Applicants traverse the rejections and supporting remarks.

For the reasons of record and those discussed herein, the specification as filed fully describes the claimed subject matter. The specification describes, in detail, how components of the *lux* operon could be obtained and re-arranged as claimed. Indeed, as admitted by the Office, the actual sequences of individual genes of the naturally occurring *luxCDABE* operon were publicly available at the time of filing. The specification discloses that *lux* operons from at least three different genera had been cloned and sequenced. (See, page 1, lines 18-20). In addition to describing precise sequences, the specification clearly describes the function and organization of *lux* operons from a variety of different bacteria:

[i]n each case, the *luxCDE* genes flank the *luxAB* genes, with transcription in the order *luxCDABE*. Although a number of additional *lux* genes have been identified in each of these three bacteria, only *luxA-E* are essential for the biosynthesis of light [citation to Meighen]. (See, page 1, lines 2-24 of the specification).

Meighen (Ref. AR-1 of IDS considered on May 31, 2002) also indicates that various exemplary *lux* operon sequences were known:

Genes coding for the bacterial luciferase subunits (*luxAB*) and the fatty acid reductase polypeptides (*luxCDE*) responsible for biosynthesis of the aldehyde substrate for the luminescent reaction have been cloned and sequenced from the *lux* operons of luminescent bacteria from three genera: *Photobacterium*, *Vibrio*, and *Xenorhabdus*. The *luxCDE* gene flank the *luxAB* genes in the different luminescent bacterial species (Fig. 1) with transcription in the order *luxCDABE* [citations omitted]. (Meighen page 1017, left column, first full paragraph).

Simply put, the specification clearly describes the structure and function of the claimed subject matter. It is axiomatic that the specification need only describe in detail that which is new or not conventional. (See, Guidelines on Written Description, page 275). In the case at hand, a skilled artisan reading the specification would have known that Applicants were in possession of claimed subject matter as recited in the claims in view of the specification's extensive disclosure of precise naturally occurring sequences from a variety of species and conventional, known methods of cloning to re-arrange these sequences. Not only were the sequences of various *lux* operon components known and publicly available at the time of filing, the specification also describes the function of these sequences and, moreover, how the naturally occurring order *luxCDABE* is re-arranged to *luxABCDE*. (See, *e.g.*, pages 28-30 and the Examples Section of the specification). In view of the disclosure of the specification and state of the art, it would have been plain to the skilled artisan that Applicants were in possession of the claimed invention at the time the specification was filed.

Turning now to the Office's assertion that there are insufficient representative species described in the specification to adequately describe the alleged "broad genus," Applicants note that a "representative number" does not mean that each and every species falling within the genus must be disclosed. (See, Guidelines on Written Description). In the pending case, multiple representative species are described, for example by reference to the various known *luxCDABE* sequences. (See, page 1, lines 18-20 and references cited therein). For the reasons noted above, it is well within the purview of the skilled artisan, in view of the teachings of the specification, to obtain *luxCDABE* sequences from any organism and re-arrange them in the manner claimed. (See, *e.g.*, page 20, lines 26-29; page 23, lines 12-20 of the specification). Accordingly, the representative number of species disclosed in the specification more than adequately conveys to the skilled artisan that Applicants were in possession of the precisely claimed molecules at the time the application was filed.

In sum, ample structure (*e.g.*, organization, order, components, sequence, function) and identifying characteristics of the claimed compositions and methods are provided so that a skilled artisan would recognize that Applicants were in possession of the claimed invention at the time of filing. As such, the written description requirement is satisfied and Applicants respectfully request that this rejection be withdrawn.

**35 U.S.C. § 112, Second Paragraph**


Claims 6-8 and 25-27 remain rejected as allegedly indefinite. (Office Action, page 4). In particular, the metes and bounds of the abbreviations recited in claims 6-8 and 25-27 are allegedly not found in the specification as filed. (Office Action, pages 4-5).

The foregoing amendments to the claims obviate the rejections under 35 U.S.C. § 112, second paragraph. In particular, the claims now recite specific sequence identifiers in reference to each designation. Accordingly, Applicants request that the rejection be withdrawn.

**CONCLUSION**

Applicants submit that the pending claims define an invention that is described, enabled and patentable over the cited references. Accordingly, Applicants submit that the claims are now in condition for allowance and request early notification to that effect. Should the Examiner have any further questions, she is invited to contact the undersigned.

Respectfully submitted,

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